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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,372	12/23/2004	Michael J. Precopio	SU 103 US	4152

7590
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03/29/2007

EXAMINER

LEVY, NEIL S

ART UNIT

PAPER NUMBER

1615

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/519,372	Applicant(s) PRECOPIO, MICHAEL J.	
	Examiner NEIL LEVY	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 and 39-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36, 39 -44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/23/04, 8/22/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The amendment filed 8/22/05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the amendment is not in proper format, & does not indicate by underlining & brackets where changes were made.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 –13,15,16,18-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific benzyl alcohol & lice, does not reasonably provide enablement for any aralkyl, and for any ectoparasites, adult, nit or nymph. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Only lice have been shown to be effectively treated, only by benzyl alcohol. There are > 647,0000 species of insects, innumerable Acarid species, & the experimentation required to determine effective control (see Lover)

Art Unit: 1615

over any one ectoparasite species with the compositions applied as

claimed is excessive.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 38 U. S. C. 112, the first paragraph have been described in re Wands, 8 USPQ2D 1400 (Fed Cir. 1988). Among these factors are (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims. (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that instant disclosure fails to meet the enablement requirement for the following reasons:

- (1) The nature of the invention: claims are to unqualified control and death by non-toxicant agents,
- (2) The state of the prior art shows the use of these compounds for specific carrier functions.
- (3) The relative skill of those in the art. The relative skill of those in the art is high.
- (4) The predictability or unpredictability of the art. The unpredictability of the art is very high.
- (5) The breadth of the claims. The claims are very broad.
- (6) The amount of direction or guidance presented. specific effects-the results expected are presumptive, no guidance given for determination if in fact the condition, disease or infestation was actually caused by inventor to not present itself.
- (7) The presence or absence of working examples. There are none showing death of pests is caused by the treatment other than Benzyl alcohol
- (8) The quantity of experimentation necessary extensive- there is no known levels of amount useful for any specific agent against any specific organism shown to exhibit death & destruction of other than lice.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1615

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1- 36 & 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lover 4368207 and Bessette 6974584 and Cardin et al 5288483, in view of Pearlman 6303581.

LOVER shows 10-40% alcohols are toxic to mites, lice & ova , depending upon the carrier system employed, & particular alcohol(col. 2, lines 35-48). Benzyl alcohol is effective @ high concentrations, phenyl ethanol @ low(Tables I-III). Some nonlimiting examples are shown- gels, shampoos.

Lover also discusses practical use (col. 2) of the alcohol compositions, & points to the artisan choosing effective amounts, exemplifying 10-40%. The data presented is that of 2 minute exposure, experimental rather than end use application.

BESSETTE also claims (claim 2) methods of using Benzyl alcohol effective to control human lice, & discusses body lotion, gel & shampoo formulations as resulting in 100% mortality of head lice(col. 3, bottom) with or without other toxicants(col. 4, top). Actives are at .01-95% (col. 6, top) of compositions. Application of shampoos to hair & scalp @ dosages determinable by the artisan (col. 6, lines 32-52) , inclusive of 0.001-5% ,by consideration of

Art Unit: 1615

many factors, is used in a suitable manner. Specific embodiments are of combination essential oils, although independent use of essential oils is expressed "-one or more-" @ col. 3, lines 11, with Benzyl alcohol a preferred compound (examples, col. 3, lines 41-43).

CARDIN also kills head lice, utilizing other of the instant formula I compounds, (col. 3) /@ 0.25-5% (col. 5, lotions, & free of conventional pesticides- these MAY be added (col. 6, LINES 22-25). CONDITIONERS, to be rinsed off, contain more active- 0.25-10% (col. 8, lines 50-63). Application & rinse off is shown at col. 12, lines 21-line 66).

PEARLMAN also treats ectoparasites of man, with barrier compositions that suffocate lice (col. 7, lines 53-63). Various regimens are described, all apply & then wash off (col. 9, col. 11, lines 9-16). Various adjuvants common to the cosmetic/pediculicidal arts, but not with toxicants, are disclosed @ col 11-13, & would be obvious & within the purview of the artisan to apply as desired.

Again, the benzyl alcohol or another alcohol of Lover, would be an added benefit to destroy the eggs & ectoparasites.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize ectoparasites pest control means, to use any of art recognized means, as of Lover, Bessette, Cardin or

Art Unit: 1615

Pearlman modified as desired to increase pesticidal efficacy without irritation or side effects, to increase stability, dispersibility, compatibility of ingredients, reduce toxicity to people infested.

The instant actives are disclosed; the instant methodology is art recognized, & illustrated in the references. The amounts and proportions of each ingredient are result effective parameters chosen to obtain the desired effects. It would be obvious to vary the form of each ingredient to optimize the effect desired, depending upon the particular species and application method of interest, reduction of toxicity, cost minimization, enhanced, and prolonged, or synergistic effects.

Applicant has not provided any objective evidence of general efficacy of formula I compounds, other than benzyl alcohol, as providing nonobvious or unexpected results. Applicant has not provided any objective evidence that the administration of the particular ingredients' or concentrations provides any greater or different level of prior art expectation as claimed, and the use of ingredient for the functionality for which they are known to be used is not basis for patentability.

The instant invention provides well known old art recognized compounds, with well known art recognized effects, applied by well known art recognized methods to achieve improved ectoparasite control as is well known in the art.

.Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

Art Unit: 1615

application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5,8-13,17-20,22-33,39-44 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim28,29,31-38. Patent No. 6793931.

Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims vary only as to concentrations and adjuvants well known & obvious to use & select in order to optimize effects, as is well known in the dermatological arts.

Claims 1-5,8-13,1520,22-33,39-44 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 33-38,44-46,48-51,65-81 of US application # 10,/382188.

Although the conflicting claims are not identical, they are not patentably distinct from each other because Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims vary

Art Unit: 1615

only as to concentrations and adjuvants well known & obvious to use & select in order to optimize effects, as is well known in the INSECTICIDAL arts .

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-5,8-13,15-20 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 30,32-36,38,45,47,49,51,54,56,58 & 60 of copending Application No. 10336457.

Although the conflicting claims are not identical, they are not patentably distinct from each other because Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims vary only as to concentrations and adjuvants well known & obvious to use & select in order to optimize effects, as is well known in the INSECTICIDAL arts

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed 8/22/05 have been fully considered but they are not persuasive. ARGUMENTS are to the effect Lover does not provide all of the elements & conditions to kill lice & ova that the instant invention has presented, but claims are broader than the scope argued, & Lover is a directive for alcohol use for ectoparasites control, with expectation of incorporation in known methods with known adjuvants & vehicles common in the lice control arts.

Art Unit: 1615

These are shown as the secondary references , also directed at lice control, & obvious to the artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL LEVY whose telephone number is 571-272-0619. The examiner can normally be reached on Tuesday-Friday, 7 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



NEIL LEVY
Primary Examiner
Art Unit 1615